5. ATTACHMENTS

MAR 8 2002

ATTACHMENT A. SPECIAL 510(k) SUMMARY

This summary of Special 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

510(k) Number:	K013662
Proprietary Name:	LipoPrint™ System LDL Subfractions
Common Name:	LipoPrint Test System (Electrophoresis)
Classification Name:	Electrophoretic Separation, Lipoproteins
Manufacturer:	Quantimetrix Corporation 2005 Manhattan Beach Boulevard Redondo Beach, CA 90278 Phone 310-536-0006 Fax 310-536-9977
Contact Person:	Neyer, Gebhard, Ph.D, Director Of R&D 310-536-0006 Ext. 135

Quantimetrix is implementing an analysis software capability to the LipoPrint™ System LDL Subfractions (previously cleared device) known as "LipoWare". The LipoWare software application is used in conjunction with commercially available hardware (computer, scanner and color printer) to analyze scanned tube images and generate high resolution graphic characterizations of lipoprotein fractions and subfractions resolved by Lipoprint (VLDL, IDL, LDL, HDL). The level of concern of the device modification was determined to be "moderate". This level of concern is for the software only. The intended use of the modified device remains the same as that of the unmodified device.

INTENDED USE AND INDICATIONS FOR USE:

The Quantimetrix Lipoprint™ System LDL Subfractions is a device intended to measure lipoprotein cholesterol (for lipoprotein fractions and subfractions from VLDL to HDL) in fasting serum or plasma with a Total Cholesterol concentration of ≥ 100 mg/dL. Lipoprotein cholesterol measurements are used as an aid in evaluating lipid metabolism disorders when used in conjunction with other lipid tests, patient risk assessment and clinical evaluation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 8 2002

Gebhard Neyer, Ph.D.
Director, Research & Development
Quantimetrix Corporation
2005 Manhattan Beach Boulevard
Redondo Beach, CA 90278-1205

Re: k013662
Trade/Device Name: LipoPrint™ System LDL Subfractions
Regulation Number: 21 CFR 862.1475
Regulation Name: Lipoprotein test system
Regulatory Class: Class I, reserved
Product Code: JHO
Dated: February 12, 2002
Received: February 19, 2002

Dear Dr. Neyer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5. ATTACHMENTS

ATTACHMENT E. INDICATIONS FOR USE FORM

510(K) NUMBER (IF KNOWN): K013662

DEVICE NAME: LipoPrint™ System LDL Subfractions

INTENDED USE AND INDICATIONS FOR USE:

The Quantimetrix Lipoprint™ System LDL Subfractions is a device intended to measure lipoprotein cholesterol (for lipoprotein fractions and subfractions from VLDL to HDL) in fasting serum or plasma with a Total Cholesterol concentration of ≥ 100 mg/dl. Lipoprotein cholesterol measurements are used as an aid in evaluating lipid metabolism disorders when used in conjunction with other lipid tests, patient risk assessment and clinical evaluation.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office Of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109) X Over-The-Counter Use

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K013662

PREPARED BY LIEN T. BAETGE